# There is a regulatory framework for mRNA- and DNA-based therapeutics and gene therapy-like vaccines. It keeps being ignored by the bureaucrats.

« *Previous* / *Next* »

The New Neander's Medical / September 7, 2021 /


Last update and review: September 7, 2021.

**Contents** [ hide ]

## A short summary.

There is a regulatory framework and national laws that impose strict safety requirements on gene therapies. The same strict requirements should apply to viral vector, DNA- and mRNA vaccines.

DNA from viral vector vaccines ALWAYS gets into the nucleus of the infected cell and modifies the host cell's genome. mRNA from mRNA vaccines would also be able to get into the nucleus of the infected cell. Both vector vaccine particles and mRNA vaccines particles were detected in testes and ovaries of vaccinated laboratory animals.

Bureaucrats and "health professionals" have not followed the existing regulatory framework and laws. Instead, they force the uninformed population to submit to injections that can potentially modify the genome of future generations of humans.

All those bureaucrats, elected officials, and "health professionals" around the world who are participating in this disastrous mass-vaccination should be criminally investigated.

## In 2014, Biontech founders, German researchers Ugur Sahin and Özlem Tureci, described the regulatory framework and risks related to gene therapy-like vaccines and other DNA and RNA medicinal products.

In 2014, Biontech founders, German researchers Ugur Sahin and Özlem Tureci, published an article on mRNA-based technologies (1). Biontech was acquired by Pfizer in 2020. Sahin and Tureci contributed significantly into the development of what became the Pfizer mRNA vaccine.

### Photo: Biontech founders Ugur Sahin and Özlem Tureci.


The 2014 article by Sahin, Tureci, and another Biontech employee Katalin Karikó (1), is reasonably informative but contains several errors. Most importantly, Sahin, Tureci, and Kariko make an error when they state: "mRNA-based therapeutics, unlike plasmid DNA and viral vectors, do not integrate into the genome and therefore do not pose the risk of insertional mutagenesis". There is a body of research that convincingly argues that nonretroviral mRNA can be integrated into the host genome. This would also be the case of the SARS-CoV-2 mRNA. Retroviruses and DNA viruses ALWAYS integrate the host cell genome.

Moller et al., 2020:

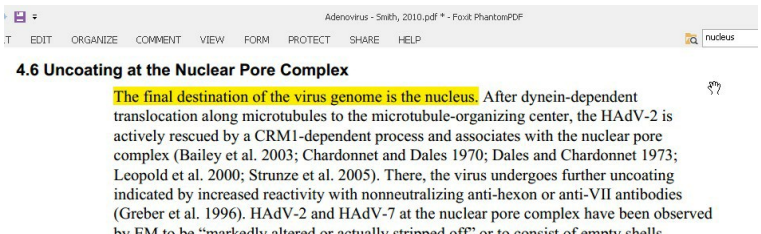
"Replication of the majority of RNA viruses takes place solely in the cytoplasm, with the exception of retroviruses, which, using reverse transcription, create a DNA provirus in the nucleus of the host cell, that is ultimately incorporated into the genome of the host."

### The final destination of adenoviruses, which are DNA viruses, is the nucleus of the infected cell, where viral DNA gets integrated into the genome of the host.

Smith, 2010 (2):

"Adenovirus (AdV) is a relatively large nonenveloped **dsDNA virus**.

…The final destination of the virus genome is the nucleus."

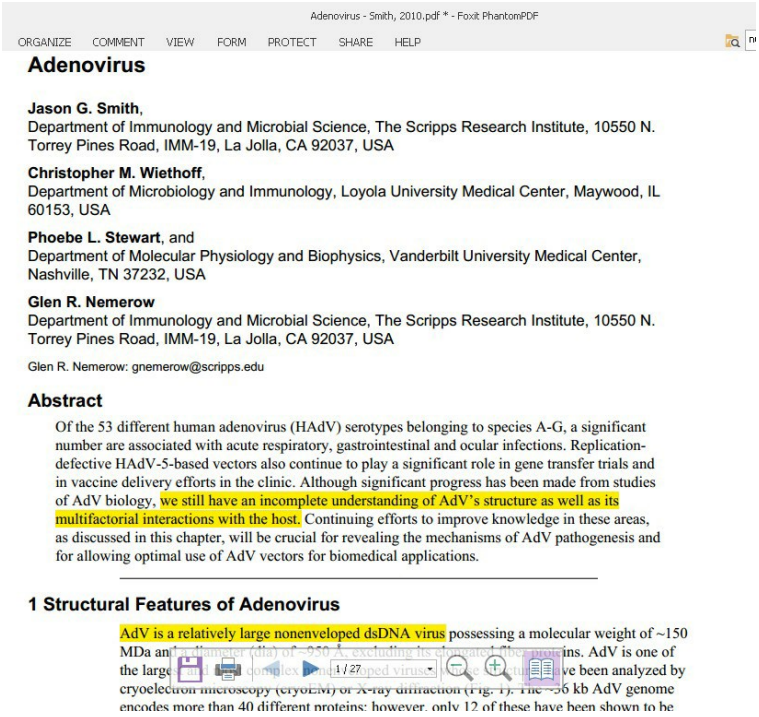


by EM to be "markedly altered or actually stripped off" or to consist of empty shells,

**"We still have an incomplete understanding of adenovirus's structure as well as of its multifactorial interactions with the host."**

Also, Smith, 2010 (2):

"We still have an incomplete understanding of AdV's structure as well as its multifactorial interactions with the host."



Adenovirus - Smith, 2010.pdf * - Foxit PhantomPDF

ORGANIZE COMMENT VIEW FORM PROTECT SHARE HELP

**Adenovirus**

**Jason G. Smith**,
Department of Immunology and Microbial Science, The Scripps Research Institute, 10550 N. Torrey Pines Road, IMM-19, La Jolla, CA 92037, USA

**Christopher M. Wiethoff**,
Department of Microbiology and Immunology, Loyola University Medical Center, Maywood, IL 60153, USA

**Phoebe L. Stewart**, and
Department of Molecular Physiology and Biophysics, Vanderbilt University Medical Center, Nashville, TN 37232, USA

**Glen R. Nemerow**
Department of Immunology and Microbial Science, The Scripps Research Institute, 10550 N. Torrey Pines Road, IMM-19, La Jolla, CA 92037, USA

Glen R. Nemerow: gnemerow@scripps.edu

**Abstract**

Of the 53 different human adenovirus (HAdV) serotypes belonging to species A-G, a significant number are associated with acute respiratory, gastrointestinal and ocular infections. Replication-defective HAdV-5-based vectors also continue to play a significant role in gene transfer trials and in vaccine delivery efforts in the clinic. Although significant progress has been made from studies of AdV biology, we still have an incomplete understanding of AdV's structure as well as its multifactorial interactions with the host. Continuing efforts to improve knowledge in these areas, as discussed in this chapter, will be crucial for revealing the mechanisms of AdV pathogenesis and for allowing optimal use of AdV vectors for biomedical applications.

**1 Structural Features of Adenovirus**

AdV is a relatively large nonenveloped dsDNA virus possessing a molecular weight of ~150 MDa an[illegible] diameter (dia) of ~950 Å, excluding its [illegible] fibers. AdV is one of the large[illegible] complex nonenveloped viruses [illegible] been analyzed by cryoelectron microscopy (cryoEM) or X-ray diffraction (Fig. 1). The ~36 kb AdV genome encodes more than 40 different proteins; however, only 12 of these have been shown to be

**Regulatory framework for mRNA-based therapeutics and for other "gene therapies".**

Sahin, Koriko, Tureci, 2014 (1):

"Existing standard guidance for new molecular entities needs to be adapted to mRNA-based drugs. So far, no competent authority has officially stated its general position on how mRNA drugs will be classified, nor have any directions and guidelines been published. As the number of precedents is limited and the diversity of mRNA-based applications is broad, one cannot predict for each individual investigational mRNA drug how the United States, the European Union and European national competent authorities may viewin vitrotranscribed (IVT) mRNA from a regulatory perspective. One would expect the classification of an mRNA drug to be a biologic, a gene therapy or a somatic cell therapy. Most of the clinical trials using IVT mRNA have been initiated by European teams and have been performed in Europe. Thus, there are not many real-life examples of how mRNA-based therapeutics would be classified by the US Food and Drug Administration (FDA)."

**The FDA definition of gene therapy is as follows: "… modification of the genetic material of living cells. Cells may be modified ex vivofor subsequent administration to humans, or may be altered in vivoby gene therapy given directly to the subject.**

Sahin, Koriko, Tureci, 2014 (1):

"The FDA definition of gene therapy is as follows: "… modification of the genetic material of living cells. Cells may be modified ex vivofor subsequent administration to humans, or may be altered in vivoby gene therapy given directly to the subject. When the genetic manipulation is performed ex vivoon cells which are then administered to the patient, this is also a form of somatic cell therapy … Recombinant DNA materials used to transfer genetic material for such therapy are considered components of gene therapy." As RNA does not result in "modification of the genetic material of living cells", one would anticipate that its administration will not be classified as a gene therapy in the United States."

**In the European Union, "Gene therapy medicinal product means a biological medicinal product which has the following characteristics: (a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; (b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence."**

Sahin, Koriko, Tureci, 2014 (1):

"In the European Union, mRNA-based therapies are most likely to fall under the European Medicines Agency (EMA)'s regulation for advanced therapy medicinal products (Directive 2009/120/EC), which covers gene therapies, engineered somatic cells and tissue engineered products. This regulation defines a gene therapy medicinal product as follows: "Gene therapy medicinal product means a biological medicinal product which has the following characteristics: "(a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; (b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence."

**Rather arbitrarily, the EU bureaucrats granted an exception to gene therapy-like vaccines.**

"Gene therapy medicinal products shall not include vaccines against infectious diseases."

Sahin, Koriko, Tureci, 2014 (1), continue:

"In vivo administered mRNA drug products are presumably viewed as an added recombinant nucleic acid complying with the EU definition of a gene therapy product. An interesting exception is dendritic cells transfected ex vivowith IVT mRNA before administration to patients. The EMA's Committee for Advanced Therapies (CAT) did not classify such a product as gene therapy because mRNA was considered to be degraded within the cells at the time of their adoptive transfer to the patient. The CAT classified this cell product as a somatic cell therapy product. Furthermore, mRNA drugs, which are used to vaccinate against infectious disease, are unlikely to be classified as gene therapy. According to Part IV of Annex I to Directive 2001/83/EC, gene therapy medicinal products do not include vaccines against infectious diseases. Moreover, the legal definition of gene therapy only relates to biological medicinal products. Consequently, products that have been manufactured by chemical means do not fulfil this definition. The guidelines established for gene therapies may provide a valuable roadmap for setting up the regulatory framework for RNA vaccines."

**Sahin, Koriko, Tureci, 2014 (1), believe that viral vector and DNA therapies and vaccines should be submitted to strong control. But their own mRNA vaccines and other therapies should not:**

"However, in contrast to DNA and viral vectors, mRNA does not contain promoter elements and does not integrate into the genome, and disruption of genes does not occur unless mRNAs encoding DNA-modifying enzymes are delivered. mRNA expression is dose-dependent and transient. Thus, there is no scientifically sound rationale to test for genome integration, germline transmission, genotoxicity or carcinogenicity of IMPs (investigational medicinal products), or carry out long-term observation of patients in clinical studies. Future guidance should take these features into consideration, as they clearly distinguish mRNA products from (other) gene therapies with respect to the anticipated risks."

**The regulatory framework and Common Sense require "to test for genome integration, germline transmission, genotoxicity or carcinogenicity of IMPs (investigational medicinal products), or carry out long-term observation of patients in clinical studies."**

**Nothing of what the regulatory framework require had been done before the vector vaccines based on DNA-viruses and mRNA vaccines were authorized and administered to hundreds of millions. How come?**

Since, as already mentioned above, Pfizer-Biontech mRNA vaccine would also be able to integrate the host cell genome, the same strict safety requirements should apply to viral vector, DNA- and mRNA vaccines. However, nothing of what the regulatory framework, and, frankly, Common Sense require had been done before the vector vaccines based on DNA-viruses and mRNA vaccines were authorized and administered to hundreds of millions. Most of the required safety measures specific to gene therapies are NOT deployed anywhere in the world to this day. How come?

Box 3 | **Regulatory framework for mRNA-based therapeutics**

Existing standard guidance for new molecular entities needs to be adapted to mRNA-based drugs. So far, no competent authority has officially stated its general position on how mRNA drugs will be classified, nor have any directions and guidelines been published. As the number of precedents is limited and the diversity of mRNA-based applications is broad, one cannot predict for each individual investigational mRNA drug how the United States, the European Union and European national competent authorities may view *in vitro* transcribed (IVT) mRNA from a regulatory perspective.

One would expect the classification of an mRNA drug to be a biologic, a gene therapy or a somatic cell therapy.

Most of the clinical trials using IVT mRNA have been initiated by European teams and have been performed in Europe. Thus, there are not many real-life examples of how mRNA-based therapeutics would be classified by the US Food and Drug Administration (FDA).

The FDA definition of gene therapy is as follows: "… modification of the genetic material of living cells. Cells may be modified *ex vivo* for subsequent administration to humans, or may be altered *in vivo* by gene therapy given directly to the subject. When the genetic manipulation is performed *ex vivo* on cells which are then administered to the patient, this is also a form of somatic cell therapy … Recombinant DNA materials used to transfer genetic material for such therapy are considered components of gene therapy." As RNA does not result in "modification of the genetic material of living cells", one would anticipate that its administration will not be classified as a gene therapy in the United States.

In the European Union, mRNA-based therapies are most likely to fall under the European Medicines Agency (EMA)'s regulation for advanced therapy medicinal products (Directive 2009/120/EC), which covers gene therapies, engineered somatic cells and tissue engineered products.

This regulation defines a gene therapy medicinal product as follows: "Gene therapy medicinal product means a biological medicinal product which has the following characteristics: "(a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; (b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence. Gene therapy medicinal products shall not include vaccines against infectious diseases."

*In vivo* administered mRNA drug products are presumably viewed as an added recombinant nucleic acid complying with the EU definition of a gene therapy product. An interesting exception is dendritic cells transfected *ex vivo* with IVT mRNA before administration to patients. The EMA's Committee for Advanced Therapies (CAT) did not classify such a product as gene therapy because mRNA was considered to be degraded within the cells at the time of their adoptive transfer to the patient. The CAT classified this cell product as a somatic cell therapy product. Furthermore, mRNA drugs, which are used to vaccinate against infectious disease, are unlikely to be classified as gene therapy. According to Part IV of Annex I to Directive 2001/83/EC, gene therapy medicinal products do not include vaccines against infectious diseases. Moreover, the legal definition of gene therapy only relates to biological medicinal products. Consequently, products that have been manufactured by chemical means do not fulfil this definition.

The guidelines established for gene therapies may provide a valuable roadmap for setting up the regulatory framework for RNA vaccines. However, in contrast to DNA and viral vectors, mRNA does not contain promoter elements and does not integrate into the genome, and disruption of genes does not occur unless mRNAs encoding DNA-modifying enzymes are delivered. mRNA expression is dose-dependent and transient. Thus, there is no scientifically sound rationale to test for genome integration, germline transmission, genotoxicity or carcinogenicity of IMPs (investigational medicinal products), or carry out long-term observation of patients in clinical studies. Future guidance should take these features into consideration, as they clearly distinguish mRNA products from (other) gene therapies with respect to the anticipated risks.

## Universal Declaration on the Human Genome and Human Rights of November 11, 1997: "human genome is the heritage of humanity."

Universal Declaration on the Human Genome and Human Rights from November 11, 1997 (3):

"Article 1:

The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. **In a symbolic sense, it is the heritage of humanity**."

**"Treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto."**

**"In all cases, the prior, free and informed consent of the person concerned shall be obtained."**

Universal Declaration on the Human Genome and Human Rights from November 11, 1997 (3):

"B. Rights of the persons concerned

Article 5

(a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.

(b) In all cases, the prior, free and informed consent of the person concerned shall be obtained."

Universal Declaration on the Human Genome and Human Rights from November 11, 1997, was adopted by "UNESCO", a "Globalist" organization. The Declaration has a lot of dubious content and promotes research. Only several passages are of interested and we cited some of them. But most of the countries have appropriate law put in place. Why the law is not followed anywhere? Why people have not been informed that their genome will be changed by vector vaccines and possibly by mRNA vaccines?

## Both viral vector and mRNA vaccines are found in testes and ovaries of the vaccinated laboratory animals. The chances are high that germline genome gets modified and will be inherited by future generations.

**On day 56(!) after vaccination, low levels of Astra-Zeneca-Oxford vaccine were noted 1 of 3 samples of ovary and testes.**

Katsura, 2019:

"5-8%(of human genome) is derived from viral sequences similar to infectious retroviruses. If integration of retrovirus occurs in germline, the integrated sequences are heritable."

Am J Med Sci. 2019 Dec; 358(6): 384–388. PMCID: PMC7093845
Published online 2019 Sep 30. doi: 10.1016/j.amjms.2019.09.007 PMID: 31813465

### Evolutionary Medicine of Retroviruses in the Human Genome

Yukako Katsura, PhD and Satoshi Asai, PhD, MD

Author information ▸ Article notes ▸ Copyright and License information Disclaimer

This article has been cited by other articles in PMC.

**Abstract** Go to:

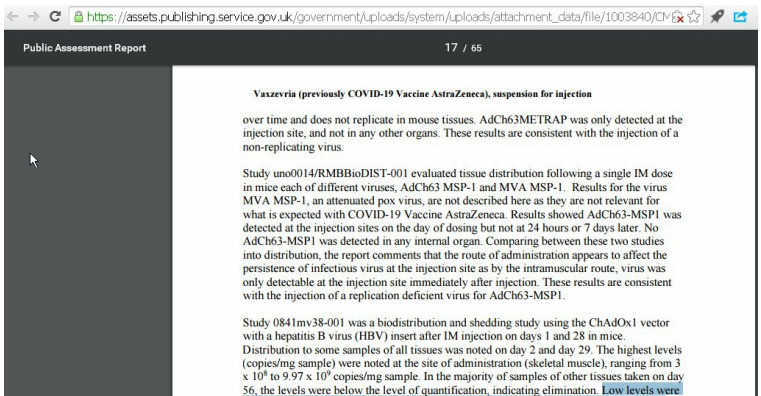
Humans are infected with many viruses, and the immune system mostly removes viruses and the infected cells. However, certain viruses have entered the human genome. Of the human genome, ~45% is composed of transposable elements (long interspersed nuclear elements [LINEs], short interspersed nuclear elements [SINEs] and transposons) and 5-8% is derived from viral sequences with similarity to infectious retroviruses. If integration of retrovirus occurs in a germline, the integrated viral sequences are heritable. Accumulation of viral sequences has created the current human genome. This article summarizes recent studies of retroviruses in humans and bridges clinical fields and evolutionary genetics. First, we report the repertories of human-infective retroviruses. Second, we review endogenous retroviruses in the human genome and diseases associated with endogenous retroviruses. Third, we discuss the biological functions of endogenous retroviruses and propose the concept of accelerated human evolution via viruses. Finally, we present perspectives of virology in the field of evolutionary medicine.

The above applies also to DNA-viruses and mRNA in vaccines. Thus, if integration of retrovirus, DNA virus used as vector in vaccines or mRNA from vaccines occurs in germline, the integrated sequences are heritable.

"Public Assessment Report – National procedure – Vaxzevria (previously COVID-19 Vaccine AstraZeneca, suspension for injection) COVID-19 Vaccine (ChAdOx1-S [recombinant])" for the UK's Medicine and healthcare regulatory agency. "Last updated in July 2021" (4):

"On day 56(!), low levels (of Astra-Zeneca-Oxford vaccine) were noted in 1 sample of 6 for each of heart and liver, **1 of 3 for ovary and testes**, and 3 of 6 lymph node samples at this timepoint"

""Distribution (of Astra-Zeneca-Oxford vaccine) to some samples of all tissues was noted on day 2 and day 29."


https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1003840/CM

Public Assessment Report 17 / 65

Vaxzevria (previously COVID-19 Vaccine AstraZeneca), suspension for injection

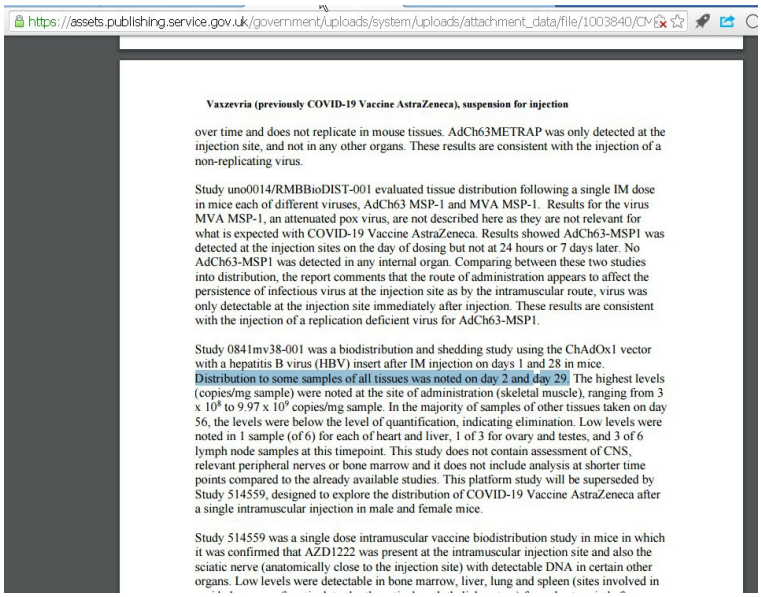
over time and does not replicate in mouse tissues. AdCh63METRAP was only detected at the injection site, and not in any other organs. These results are consistent with the injection of a non-replicating virus.

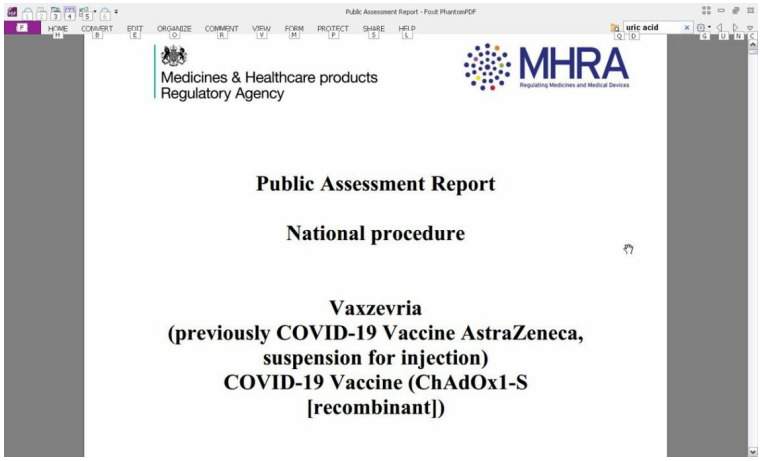
Study uno0014/RMBBioDIST-001 evaluated tissue distribution following a single IM dose in mice each of different viruses, AdCh63 MSP-1 and MVA MSP-1. Results for the virus MVA MSP-1, an attenuated pox virus, are not described here as they are not relevant for what is expected with COVID-19 Vaccine AstraZeneca. Results showed AdCh63-MSP1 was detected at the injection sites on the day of dosing but not at 24 hours or 7 days later. No AdCh63-MSP1 was detected in any internal organ. Comparing between these two studies into distribution, the report comments that the route of administration appears to affect the persistence of infectious virus at the injection site as by the intramuscular route, virus was only detectable at the injection site immediately after injection. These results are consistent with the injection of a replication deficient virus for AdCh63-MSP1.

Study 0841mv38-001 was a biodistribution and shedding study using the ChAdOx1 vector with a hepatitis B virus (HBV) insert after IM injection on days 1 and 28 in mice. Distribution to some samples of all tissues was noted on day 2 and day 29. The highest levels (copies/mg sample) were noted at the site of administration (skeletal muscle), ranging from 3 x $10^8$ to 9.97 x $10^9$ copies/mg sample. In the majority of samples of other tissues taken on day 56, the levels were below the level of quantification, indicating elimination. Low levels were

noted in 1 sample (of 6) for each of heart and liver, 1 of 3 for ovary and testes, and 3 of 6 lymph node samples at this timepoint. This study does not contain assessment of CNS, relevant peripheral nerves or bone marrow and it does not include analysis at shorter time points compared to the already available studies. This platform study will be superseded by Study 514559, designed to explore the distribution of COVID-19 Vaccine AstraZeneca after a single intramuscular injection in male and female mice.

Study 514559 was a single dose intramuscular vaccine biodistribution study in mice in which it was confirmed that AZD1222 was present at the intramuscular injection site and also the sciatic nerve (anatomically close to the injection site) with detectable DNA in certain other organs. Low levels were detectable in bone marrow, liver, lung and spleen (sites involved in

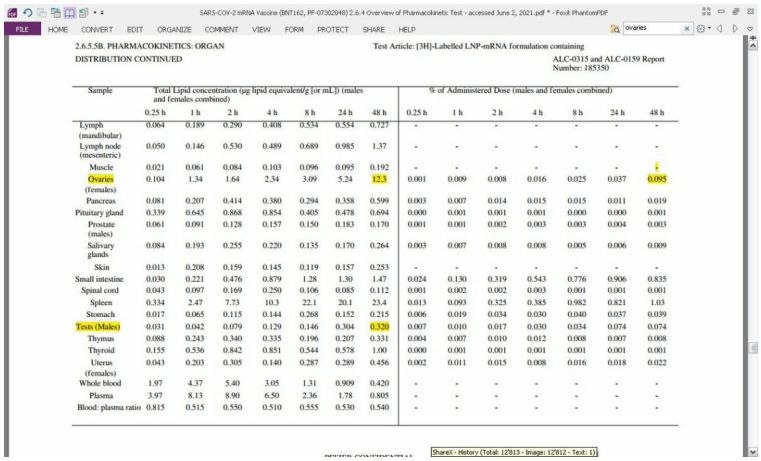


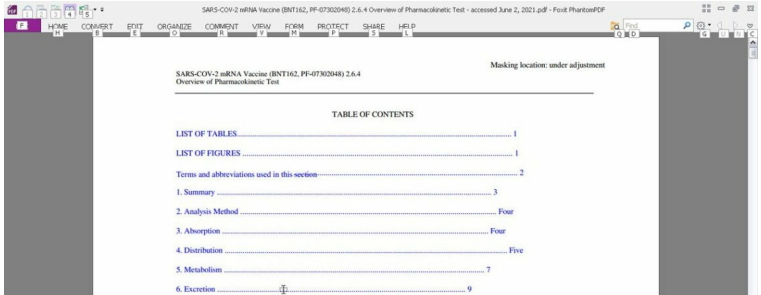



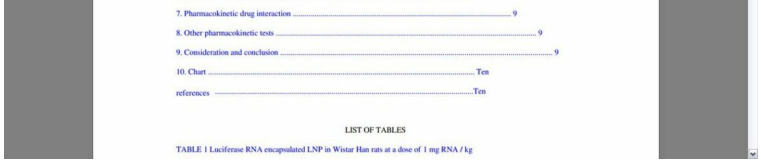

**A lot" of injected mRNA ends in ovaries. 9% or 0.09%? Pfizer's documents contain a lot of errors. But it appears to be 50% of mRNA that gets in spleen."**

The New Neander's Medical on June 2, 2021:

"There is a document that is circulating on the networks that allegedly describes Pfizer COVID-19 vaccine's pharamcokinetics. "A lot" of injected mRNA ends in ovaries. 9% or 0.09%? Pfizer's documents contain a lot of errors. But it appears to be 50% of mRNA that gets in spleen."






## Conclusions.

Bureaucrats and "health professionals" have been ignoring the existing regulatory framework and laws. Instead, they force the uninformed population to submit to injections that can potentially modify the genome of future generations of humans.

All those bureaucrats, elected officials, and "health professionals" around the world who are participating in this disastrous mass-vaccination should be criminally investigated.

## Selected references:

1. Ugur Sahin, Katalin Karikó, Özlem Türeci. mRNA-based therapeutics — developing a new class of drugs. . Nat Rev Drug Discov. 2014 Oct;13(10):759-80. doi: 10.1038/nrd4278. Epub 2014 Sep 19. PMID: 25233993.

2. Smith. Adenovirus. Curr Top Microbiol Immunol. 2010 ; 343: 195–224.

3. Universal Declaration on the Human Genome and Human Rights from November 11, 1997.

Available at:

http://unesdoc.unesco.org/images/0011/001102/110220e.pdf#page=47

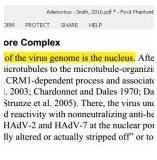
Accessed on September 7, 2021.

4. "Public Assessment Report – National procedure – Vaxzevria (previously COVID-19 Vaccine AstraZeneca, suspension for injection) COVID-19 Vaccine (ChAdOx1-S [recombinant])" for the UK's Medicine and healthcare regulatory agency. "Last updated in July 2021".

Available at:

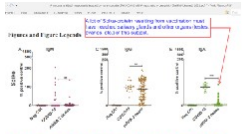
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1003840/CMA_UKPAR_COVID_19_Vaccine_AstraZeneca_PAR_16.07.2021.pdf

Accessed on September 7, 2021.

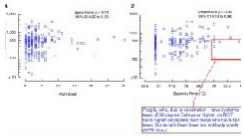




DNA from virus vector vaccines always integrate into the genome of the infected cell. SARS-CoV-2 mRNA from mRNA vaccines would also be able to integrate human genome.
September 7, 2021
With 4 comments



Human saliva is apparently good at neutralizing viruses WITHOUT any vaccination and virus-specific antibodies. A study by Sheikh-Mohamed et al., 2021.
August 21, 2021
Similar post



Pfizer's BNT162b2 mRNA vaccine: "no correlation was seen between levels of neutralizing antibodies ("NT50s") and adverse effects ("AEs")".
August 22, 2021
With 3 comments

DNA from virus vector vaccines always integrate into the genome of the infected cell. SARS-CoV-2 mRNA from mRNA vaccines would also be able to integrate human genome.

Curcumin alone is not senolytic – a study by Beltzig et al., 2021.

## Published by The New Neander's Medical

View all posts by The New Neander's Medical

## Leave a Reply

Enter your comment here

Search …

Search



**Recent Posts**

adverse effects ("AEs")".

Human saliva is apparently good at neutralizing viruses WITHOUT any vaccination and virus-specific antibodies. A study by Sheikh-Mohamed et al., 2021.

Tan et al., 2021 (1): Serum of (two of the eight) patients who survived SARS-CoV-1 infection 17 years ago, and were vaccinated with mRNA vaccine against SARS-CoV-2, inhibited by 100% all variants of SARS-CoV-2 and many bat CoVs.

"Standing desk" is to avoid. A Summary Statement.

Maeda and coworkers, 2021: "Both young and older vaccinated individuals with good neutralization response would lose mRNA vaccine protection in 6 to 7 months after the 1st dose."

A Test: Predict the levels of thyroid hormones, TSH, T3, fT3, T4, and fT4, in these cyclists: "Young elite cyclists can handle 700 grams of carbs and 4800 kCal of total calories a day without apparent metabolic damage."

Causes of constipation, osmotic laxatives and prokinetics, safety of polyethylene glycol/macrogol (PEG). Our comments and notes.

A review of Johnson & Johnson's COVID-19 adenovirus vector vaccine.

Tests of thyroid hormones. A summary statement.

Essentials of RT PCR and other molecular diagnostic for COVID-19. Infection spread by mass PCR-testing.

A Test of Physiological Literacy: Can exercise cause hyperinsulinemia?

COVID-19. A "Certificate of Civil Protection Aptitude During Epidemics": learn to avoid pathogens.

A Test of Physiological Literacy: can you explain the mechanism of ketoacidosis in 280 characters?

Draw a curve that shows desirable blood glucose levels during a day. A Test.

How much protein and fat a day should an endurance athlete consume to cover his daily glucose expenditure? A Test.

Protected: "An Advantaged Metabolic State" or a nuisance? Adding blood ketones to the list of markers for self-monitoring.

Young elite cyclists can handle 700 grams of carbs and 4800 kCal of total calories a day without apparent metabolic damage.

Protected: IGF-1 and insulin during fasting and on restrictive diets.

Probiotic use can predispose to overgrowth of methanogenic bacteria.

Low TSH and osteoporosis.

High LDL particle number: is it really an indication of insulin resistance and/or of an increased risk of heart disease?

The New Neander's Challenge: Who has the highest uric acid?

"Healthy fat" and serum uric acid.

Hyperuricemia.

COVID-19 update: no herd immunity for the "dumb", masks do NOT work, "virus denial" does not work.

The New Neander's workouts: brisk walking.

A Working Group on low testosterone in overweight and obese men: is it a good idea to suppress LH with testosterone replacement therapy in asymptomatic men?

Uric acid in athletes in Stephen Phinney's early studies.

Protected: Treatment of COVID-19 in Geneva, Switzerland.

Urinary creatinine.

R-effective of SARS-CoV-2 is “infinite”: in many households, if one person gets infected, all the other household members will be infected as well.

Protected: The problem with collagen. Digestive health.

Postprandial workouts for eating disorders, mood disorders, digestive health, better sleep, fat loss.

Protected: The New Neander’s Challenge: What geographic areas can keep R-effective below 1?

Meat and vegetables bouillon or “consommé”.

The New Neander’s Challenge: Who has the highest SHBG?

Protected: Periodic reviewing (reading again) of interesting studies is something that we recommend to medical practitioners, researchers, and people who follow our courses in Physiological Literacy.

Nose warming.

Protected: SARS-CoV-2 “R-effective” as a measure of population’s IQ.

A “Freedom of Speech” page for the article “Another load of absurdities from the strange doctor Paul Mason.”

Typing long texts without ever looking at the computer screen.

“Non-susceptible” versus “Immune” and Epidemiology as a branch of propaganda.

Protected: A lot of men on low-carb diets walk with high SHBG. Is this metabolic profile safe?

Protected: Defining the wild-type carnivore diet: protein and fat intakes, metabolic profiles, etc. A Working Group.

Does diamine oxidase (DAO) contained in pork kidney remain active after cooking? And do DAO supplements work?

CAC score can decrease over time in a notable proportion of people.

Low-carb high-fat diet (LCHF) dangerously resembles the “high-fat diet” that induces disease and chronic inflammation in mice.

Protected: Raoult’s IHU hospital is not “the best” anymore: mortality is not zero and is in line with countries that don’t necessarily use hydroxychloroquine. The verdict: Over-fixation on HCQ, under-estimation of steroids, incompetent ICU.

Phinney and Volek since 2011 say: “Above 1 mmol/L (of blood ketones), more than half of the brain’s fuel comes from ketones.” A Test: is this true?

A serious error in the way Volek et al. designed their 2016 FASTER study.

“Primitivism” of online health educators: extreme naiveté in interpretation and treatment of subjects.

Another load of absurdities from the strange doctor Paul Mason.

A Test: What is wrong in the diagram of the lipoprotein cycle that the health educator Dave Feldman put in his profile on a social network?

Protected: An introduction to self-monitoring: blood glucose, blood pressure and other essential markers.

Postprandial triglycerides on low-carb and high-carb diets.

Thyroid-stimulating hormone (TSH) and physical activity.

Insights from magnetic resonance imaging of the colon and small intestine.

Gall bladder contracted by 42% after 10 grams of fat.

Measurable changes in serum IL-17 (decrease) and IL-10 (increase) in an animal model of arthritis after Lactobacillus sakei

administration.

A Working Group on SHBG.

Cooking losses of minerals in foods.

A call for suppliers of complete blood count analyzers for capillary blood.

Protected: Paul Saladino's diet of "raw testicles and 120 grams of honey a day": how to destroy your metabolic profile in one year. Anthropology.

Protected: Self-monitoring, an introduction for a new consulting client.

A call for suppliers of blood pressure measuring devices for our clients and community.

A Test: Do postprandial triglycerides always rise after a high-fat meal?

Combined hydroxychloroquine and azithromycin show synergistic effect on SARS-CoV-2 in monkey Vero E6 cells in vitro but may not be effective in human alveoli, pneumocytes and other cells.

The ability of IFN-gamma to inhibit replication of viruses correlated with the cells' production of nitric oxide (NO).

The Th1-Th2 paradigm provides a framework for understanding T cell biology and the interplay of innate and adaptive immunity.

A Test: Are there any athletes in the two groups who are insulin-resistant?

Eicosanoid biosynthesis from arachidonic acid (20:4n-6).

The difference between anti-inflammation and pro-resolution.

COX-2 and the natural signaling pathways in resolution of acute lung injury.

Classification of fatty acids.

Simethicone: "it is possible that the liberated GI gas is more readily absorbed through the intestinal mucosa into the blood stream because of the change in surface tension and the reduction of adherent mucus."

HCQ+AZ, the pre-therapy workup and the follow-up: electrolytes, electrocardiogram with corrected QT (Bazett's formula) and more.

A test: Calculate the in-hospital mortality in the patients that did not receive either hydroxychloroquine or azithromycin in Marseille, France.

New York: Only 3% of COVID-19 patients on mechanical ventilation made it out of hospitals alive (as of April 4, 2020).

"Exposure to bile salts constituted a highly aggressive stress for Saccharomyces boulardii, since all the cells died after 1 h of this treatment.

Capillary Blood Sampling (by Katja Lemburg).

Comparison of Complete Blood Count between Venous and Capillary Blood.

A test: estimate sensitivity and specificity of fever as a test for COVID-19 in a group of subjects.

Identical epidemic curves of COVID-19 in Belarus (zero lockdowns) and the US in Arpil-June 2020.

Systolic blood pressure below 90mmHg and assessment of COVID-19 severity with "CRB-65" score.

Terminology: use "specialist" instead of "expert".

42% seroprevalence for SARS-CoV-2 in an Austrian town. A majority of seropositives reported taste and smell disorders.

"Rethinking the early intubation paradigm." Analysis: It was never a "paradigm" but hardcore malpractice.

Azithromycin in UK's RECOVERY trials.

Raoult on flu, antibiotics and viral infections

in the French Senate in 2012.

COVID-19 management in Singapore.

ACE2 expression in organs and systems most frequently affected in COVID-19.

Fauci, a strange 79 years old character, who has been involved in sabotage for over 30 years, suddenly warns COVID-19 vaccines can be dangerous.

Hepatitis B vaccine: only 25% of adults aged above 40 developed antibodies. 75% remained unprotected.

Protected: The current state of Human Civilization: 5 months to start figuring out the obvious during the COVID-19 epidemic.

A study from China found that hydroxychloroquine was ineffective in the treatment of mild to moderate COVID-19. Despite a high dose and long administration.

Chaotic treatment of COVID-19 patients in New York State.

Lymphocytes, neutrophils and IL-6 and the "Effects of Ageing on the Immune System".

Treatment of COVID-19 in Marseille, France.

Protected: Tracking your food and nutrient intakes.

COVID-19 in Belarus is reaching a plateau.

The current "standards of care" for the treatment of COVID-19: "stay at home, and when you can't breathe anymore, come to the hospital to die".

China may be telling the truth about the low number of COVID-19 cases: scientists there struggled to recruit patients for their studies.

Didier Raoult: "We did not test antibiotics against viruses. Now we do and we realize that a lot of antibiotics are effective against viruses."

Chinese Clinical Guidance for COVID-19 Diagnosis and Treatment (7th edition), updated March 16, 2020.

What proportion of SARS-CoV-2 infections are asymptomatic?

Chronic administration of hydroxychloroquine in systemic lupus erythematosus (SLE): it is not known yet if it is protective against COVID-19 (April 30, 2020).

Ethnicity does NOT affect the risks in COVID-19. Vitamin D status may not either.

The "Korean diet": only 30 grams of fat a day. A "Korea-nivore diet"?

A rare good move: the World Health Organization criticized "immunity passports" (April 24, 2020).

Catastrophic COVID-19 mortality rates among the hospitalized males in the New York City area: above 80 years old – 60.6%, 70-79 years old – 35.8%, 60-69 years old – 18.7%, 50-59 years old – 12.2%, 20-49 years old – around 7%.

Physiological Literacy on mechanical ventilation in COVID-19: "Only a small proportion of patients—largely those in a cardiac arrest situation—"require" mechanical ventilation."

Monastyrsky's probiotic supplement.

Obesity is NOT associated with severe COVID-19. Age and hypertension are. Studies from Wuhan (452 patients), Marseille (1061 patients) and New York (1150 patients).

France keeps breaking records in the COVID-19 mortality rate: 17.66% (as of April 20, 2020). Other "leading European countries" are catching up with France.

T-cell response to respiratory virus infections.

Early detection of COVID-19: "If you don't feel the taste of salt (ageusia); if you lose the sense of smell (anosmia)." KB.

T cell-mediated immune response to

respiratory coronaviruses and vaccines against SARS-CoV that induce immunopathology.

COVID-19 vaccines are unlikely to protect those who are at a higher risk. A 2006 study: Vaccines fail to generate protective immunity in 50% to 90% of older individuals.

The White House has finally figured out that “Voice of America” spreads foreign propaganda (April 10, 2020).

Anemia in COVID-19 patients: an innate immune response? “Hepcidin-mediated iron sequestration protects against bacterial dissemination during pneumonia.”

Which of the statements on COVID-19 therapies are correct? A Test.

Long walks to heal joints and ligaments. Tools.

Inactivation of SARS-CoV-1 by alcohol (ethanol).

Preparedness audit: are you ready to deal with COVID-19?

Idiotic medical doctors turned COVID-19 into a Plague: in France, COVID-19 mortality rate in hospitalized patients is reaching 23%, and, on average, it is 14.28% (as of April 10, 2020).

Definitions of Minimal cytotoxic concentration (MCC), Cytotoxic concentration (CC50), Effective concentration (EC50), Inhibitory concentration (IC50), and Selectivity index (SI).

Aqueous extract from Urtica dioica reduced E. coli biofilm production.

Novartis stated they have 50,000,000 doses on hand with another 80,000,000 doses to be ready by May.

On April 8, 2020, France hit a gruesome record as its COVID-19 mortality rate reached 13.35%. Causes: sabotage of bureaucracy and medical incompetence.

SARS-CoV utilizes angiotensin-converting enzyme 2 (ACE2) to infect host cells. What is ACE2?

Corticosteroid administration depletes lymphocytes and increases neutrophils in peripheral circulation.

High doses of corticosteroid methylprednisolone for 1–2 days early in the course of acute respiratory distress syndrome (ARDS) may be harmful.

There is an antibody-dependent enhancement (ADE) of SARS-CoV-1 infection. Notably, some vaccines enhance infection.

A 2020 study: young subjects vaccinated with flu vaccine had a 36% higher risk to be infected with a coronavirus.

There was a systematic use of corticosteroids at early stages of COVID-19 by doctors in China.

Two other common coronaviruses do not fulfill Koch’s postulates.